No. 83-196

IN THE

Supreme Court of the United States

OCTOBER TERM, 1983

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR,
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
Appellant,

v.

MONSANTO COMPANY

On Appeal from the United States District Court for the Eastern District of Missouri

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BRIEF OF THE PESTICIDE PRODUCERS ASSOCIATION, DREXEL CHEMICAL COMPANY, FALLS CHEMICALS, INC., AND GRIFFIN CORPORATION AS *AMICI CURIAE*

DAVID B. WEINBERG *
WILLIAM R. WEISSMAN
SUSAN D. SAWTELLE

WALD, HARKRADER & ROSS
1300 Nineteenth Street, N.W.
Washington, D.C. 20036
(202) 828-1200

Attorneys for the Pesticide Producers Association, Drexel Chemical Company, Falls Chemicals, Inc., and Griffin Corporation

* Counsel of Record

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BRIEF OF THE PESTICIDE PRODUCERS ASSOCIATION, DREXEL CHEMICAL COMPANY, FALLS CHEMICALS, INC., AND GRIFFIN CORPORATION AS *AMICI CURIAE*

INTEREST OF *AMICI CURIAE*

The Pesticide Producers Association ("PPA") is a voluntary nonprofit group of approximately forty companies engaged primarily in producing, formulating and distributing agricultural pesticides in the United States. Members of PPA provide a direct link to the American farmer. In contrast to larger domestic and international companies, PPA members generally serve local and regional markets. Three of its member companies (Drexel Chemical Company, Falls Chemicals, Inc. and

Griffin Corporation) join with PPA in filing this brief to illustrate the drastic impact that affirmance of the decision below would have on PPA member companies and other small pesticide companies, the American farmer and the consuming public. Both parties to this case have consented to the filing of this brief; letters so indicating are filed herewith.

Drexel Chemical Company is a privately-held Tennessee corporation based in Memphis, Tennessee. Drexel does business primarily in the central and southeastern United States and has annual domestic sales of approximately $25 million. Its principal pesticide products are atrazine, dinitro and methyl parathion, used on a variety of crops including corn, beans, and fruit crops. Over 75% of Drexel's revenues are derived from products registered under the regulatory scheme invalidated by the district court in this case, and more than thirty applications filed by Drexel under the scheme are pending with the Environmental Protection Agency ("EPA").

Falls Chemicals, Inc. is a privately-held Montana corporation headquartered in Great Falls, Montana. It sells its products in nine western states and has annual sales of approximately $2 million. The company specializes in herbicides made with 2, 4-dichlorophenoxyacetic acid and/or 2-methyl-4-chlorophenoxyacetic acid, which are used mainly on grain crops such as corn, wheat and oats. These and all its other products have been registered with EPA under the statutory scheme invalidated by the district court.

Griffin Corporation is a privately-held Georgia corporation headquartered in Valdosta, Georgia, with additional manufacturing facilities in Texas. Its products are sold primarily in California, Florida and Georgia. Griffin's annual sales volume is less than $50 million, about 65% of which derives from the sale of products, such as linuron, which are registered under the invali-

dated scheme. It, too, has several registration applications pending with EPA.

Until struck down by the court below, the pesticide registration scheme established by the Federal Insecticide, Fungicide, and Rodenticide Act, *as amended*, 7 U.S.C. §§ 136a-136y (1982) ("FIFRA"), assured competition in the pesticide industry by enabling PPA's member companies and other small pesticide marketers to obtain product registrations without the burdens and delays involved in having to assemble individually the costly and duplicative health and safety data on which registrations are based.[1] Significantly, the scheme did not give one pesticide marketer access to the data produced by another company, or to another's product formulas or manufacturing processes. It simply permitted the agency to use information in its own files to determine that a subsequent applicant's product was safe and effective and hence eligible for registration.

Thousands of "follow-on" (also known as "me-too") pesticide products have been registered under this scheme, and thousands more are expected to be granted if the Court upholds the statute. However, if the Court affirms the district court's conclusion that the Fifth Amendment denies Congress the power to adopt this regulatory scheme, almost every small pesticide formulator and producer is likely to be forced out of the market. This result is diametrically contrary to Congress' assessment of the public interest. Even as to those few companies that might be able to afford the testing needed to support a registration, requiring them to do so will waste

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[1] EPA recently found that the 1980-81 cost of the testing necessary to support a registration was approximately $1.9 million to $2.8 million per active ingredient. *See* EPA, REGULATORY IMPACT ANALYSIS: DATA REQUIREMENTS FOR REGISTERING PESTICIDES UNDER THE FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT 14-15, 70, 72 (1982). PPA members' experience shows that these figures may be understated.

scarce scientific resources and millions of dollars, again in conflict with Congress' perception of the public interest.

The parties' briefs undoubtedly will address fully the profound constitutional issues presented by this case. In filing this brief as *amici curiae*, our principal aim is not to duplicate those arguments, but to describe the practical ramifications of invalidating the key registration provisions of FIFRA. As we shall show, a decision that the Constitution requires each applicant for a pesticide registration to assemble health and safety data—even if it duplicates data already in EPA's files on the same product—is likely to cause the demise of a significant portion of the American pesticide industry.

SUMMARY OF ARGUMENT

I.

Relying primarily on legal principles of a bygone constitutional era, the district court struck down the heart of the pesticide regulatory scheme fashioned by Congress in the 1970s. That scheme embodies four basic objectives: (1) to assure the public that all pesticides sold in the United States are effective and will not unreasonably harm the environment; (2) to streamline the regulatory process to eliminate waste and duplication of effort; (3) to minimize possible disincentives to innovation by spreading the cost of assembling data among all registrants that benefit from the data; and (4) to minimize the barriers to market entry resulting from regulatory requirements and eliminate the *de facto* extension of patent protection that otherwise would result. Congress grappled with balancing these goals for over six years, and concluded that they could best be achieved by authorizing EPA to conclude that pesticide products are safe and effective on the basis of health and safety data already placed in the Agency's files by registrants of

equivalent products, as long as the subsequent registrants agree to share the cost of producing the data.

Congress' judgment of how best to serve these public purposes has proven correct. The record since this statutory scheme was adopted reveals substantially increased competition in the pesticide market, resulting in lower prices to the farmer and ultimately to the consumer; a more efficient regulatory process; and adequate incentives to product innovation. If the Court affirms the decision below and invalidates the follow-on scheme, however, the additional funds that each registrant will be required to spend to comply with FIFRA's testing requirements for future registrations will be so substantial that virtually no small pesticide company will remain a viable force in this industry. This result will be compounded if existing follow-on registrations are voided, as urged by several companies that originally submitted the data on which those registrations are based. Affirmance of the decision below thus would totally eviscerate the pesticide registration scheme Congress designed to serve the public interest.

II.

Contrary to the view of the district court, nothing in the Fifth Amendment compels the calamitous results described above. In holding that FIFRA unconstitutionally effected a taking of Monsanto's property, the district court misapplied the principles of *Penn Central Transportation Co. v. New York City*, 438 U.S. 104 (1978), by overstating the nature of Monsanto's property interest in data it had voluntarily turned over to EPA and disregarding the manifest public purposes of the Act.

III.

In addition to striking down FIFRA's follow-on registration scheme, the district court held the Act's arbitration provision unconstitutional because it purportedly

does not afford just compensation to remedy the Fifth Amendment "taking." However, if there is no "taking," there is no requirement for just compensation and no need to decide whether the arbitration scheme affords it. Moreover, the decision below on the constitutionality of the arbitration provision was premature because Monsanto has not invoked the arbitration mechanism to resolve a compensation dispute with a follow-on registrant and it is speculative whether it ever will. Accordingly, regardless of how this Court resolves the "taking" question, it should reverse the judgment concerning the arbitration scheme and, to that extent, direct the district court to dismiss the complaint.

ARGUMENT

I. THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT, AS AMENDED, PROTECTS THE ENVIRONMENT FROM UNSAFE AND INEFFECTIVE PESTICIDES WHILE PROMOTING COMPETITION AND INNOVATION.

Congress has regulated the sale of agricultural fungicides and pesticides in interstate commerce for nearly seventy-five years. *See Chevron Chemical Co. v. Costle*, 641 F.2d 104, 106 (3d Cir.), *cert. denied*, 452 U.S. 961 (1981) (citing Insecticide Act of 1910, c. 191, 36 Stat. 335). In the 1970s, Congress undertook, in three successive sets of amendments, to achieve the appropriate balance between several competing interests while assuring the safety and efficacy of pesticides vital to the nation's farm economy. In this section of the brief, we review Congress' effort to grapple with these issues, then demonstrate that the legislation has accomplished precisely what Congress intended and describe the devastating impact of striking it down.

A. Congress Developed a Carefully Balanced Regulatory Scheme to Eliminate Wasteful Duplication of Testing and Minimize Regulatory Barriers to Market Entry While Rewarding Innovation.

Congress first required registration of pesticide products as a precondition for their sale in interstate commerce in 1947. To obtain such a registration, the applicant was required to submit test data showing that the product was safe and effective. FIFRA §§ 2-13, 61 Stat. 163-72 (1947).

Until 1972, the registration agency used information in its files already provided by a prior registrant in approving follow-on registration applications without obtaining permission from the original data submitter, but did not disclose the information to later applicants.[2] In 1972, responding to several concerns, including that follow-on applicants could obtain an unfair cost advantage over those companies that undertook the required testing and that the existing system provided disincentives for innovation, Congress amended the statute. As modified, FIFRA directed that if the agency used information previously submitted by one registrant to approve a second company's follow-on application, the follow-on applicant must first offer to pay "reasonable compensation" to the initial registrant. FIFRA § 3(c)

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[2] *See Chevron Chem. Co. v. Costle*, 641 F.2d at 109 (citing EPA, OFFICE OF PESTICIDE PROGRAMS, FIFRA: IMPACT ON THE INDUSTRY, *reprinted in* S. REP. NO. 334, 95th Cong., 1st Sess. 34 (1977)); *Union Carbide Agric. Prods. Co. v. Costle*, 632 F.2d 1014, 1016 (2d Cir. 1980), *cert. denied*, 450 U.S. 996 (1981); *Amchem Prods., Inc. v. GAF Corp.*, 594 F.2d 470, 472 (5th Cir.), *modified on other grounds*, 602 F.2d 724 (5th Cir. 1979); *Mobay Chem. Corp. v. Costle*, 517 F. Supp. 252, 267 n.11 (W.D. Pa. 1981), *aff'd sub nom. Mobay Chem. Corp. v. Gorsuch*, 682 F.2d 419 (3d Cir.), *cert. denied*, 459 U.S. ——, 103 S. Ct. 343 (1982); *Mobay Chem. Corp. v. Costle*, 12 Env't Rep. Cas. (BNA) 1572, 1580 n.22 (W.D. Mo. 1978), *appeal dismissed for want of jurisdiction*, 439 U.S. 320 (1979); S. Rep. No. 838, pt. 2, 92d Cong., 2d Sess. 18-19, *reprinted in* 1972 U.S. CODE CONG. & AD. NEWS 3993, 4040.

(1)(D), Pub. L. No. 92-516, 86 Stat. 979 (1972). *See Chevron Chemical Co. v. Costle*, 641 F.2d at 107. Congress also added new provisions to the statute designed to protect prior registrants' trade secrets.[3] Significantly, however, Congress refused to give data submitters the right to exclusive use of their own data. It thus evidenced concern that an exclusive use scheme would confer anticompetitive, quasi-patent privileges on registered products, even after their patents had expired or where the product consisted of unpatentable common chemicals in the public domain.[4]

However, the 1972 amendments did not achieve Congress' aims. Because FIFRA contained no definition of the term "trade secrets," the 1972 amendments, in effect, gave data submitters unrestricted authority to label any portion of their data submissions as trade secret material and to bind the agency to that characterization.

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[3] Section 10(a) of the 1972 Act, Pub. L. No. 92-516, 86 Stat. 989, permitted an applicant to designate portions of the data as trade secrets, while section 10(b) prohibited the agency from disclosing material designated as trade secrets under section 10(a) except as necessary to carry out its statutory duties. The Trade Secrets Act, 18 U.S.C. § 1905 (1982), also prohibited government officials from disclosing trade secrets to the public.

[4] Congress repeatedly expressed concern that the registration system could extend patent monopolies beyond those authorized by the patent system. The Senate Committee on Commerce deleted an "exclusive use" provision in the 1972 bill because

> barriers to entry in the pesticides industry would result which go far beyond that envisioned by our patent system. In effect, whether or not a pesticide has patent protection, a manufacturer wishing to register a pesticide previously registered would have to duplicate the required test data . . . . In the extreme, a monopoly in the production of a pesticide could ensue if competitors are unable to afford the sometimes costly safety and efficacy tests.

S. REP. No. 970, 92d Cong., 2d Sess. 12, *reprinted in* 1972 U.S. CODE CONG. & AD. NEWS 4092, 4096. *See also id.* at 14, 16, *reprinted in* 1972 U.S. CODE CONG. & AD. NEWS at 4098, 4100.

Furthermore, because section 3(c)(1)(D) also prohibited the agency from relying on data labelled by the submitter as a "trade secret," the practical utility of the data reliance scheme was severely limited.

Congress sought to narrow the competitive restrictions established in the 1972 amendments when it again amended the statute in 1975. Pub. L. No. 94-140, 89 Stat. 751. Among other modifications, Congress expressly eliminated any compensation requirements for reliance on data submitted before 1970, and required payment of such compensation only from applicants whose registration applications were filed after October 21, 1972. 89 Stat. 755 (1975).[5]

Despite Congress' intentions, the overall effect of the 1972 and 1975 amendments was an "administrative nightmare in which the process of registering new pesticides simply ground to a halt." *Chevron Chemical Co. v. Costle*, 641 F.2d at 111. This proved to be a complete bar to new market entry. *Id.* Congress thus again revisited the regulatory scheme in 1978. Pub. L. No. 95-396, 92 Stat. 819.

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[5] This amendment left in place the agency's prior practice of using pre-1970 data in its files to determine the safety and efficacy of products covered by follow-on applications without compensating the initial registrant, and also the provision that barred the agency from relying on data submitted after 1970 designated under section 10(a) by the submitter as a trade secret.

The constitutionality of this data reliance program was upheld by a three-judge district court in *Mobay Chem. Corp. v. Costle*, 12 Env't Rep. Cas. (BNA) 1572 (W.D. Mo. 1978). A direct appeal to this Court was dismissed because the Court concluded that a three-judge court had been improperly convened. *Mobay Chem. Corp. v. Costle*, 439 U.S. 320 (1979) (per curiam). Justice Blackmun concluded in dissent, however, that the agency's practice of using such data for follow-on applications without compensation was ratified by Congress in the 1975 amendments and that the three-judge court accordingly had been properly convened. Based on this reasoning, he believed that this Court had jurisdiction over the appeal. On the merits, he concluded that the district court had correctly upheld the constitutionality of the practice. *Id.* at 321.

In response to strong complaints from EPA, the Department of Justice, and others about the ineffectiveness of the 1972 and 1975 amendments in promoting competition, further amendments to section 3(c)(1)(D) were adopted.[6] Congress reaffirmed the agency's right to use data in its files for follow-on registrations, subject to an arbitration procedure to resolve disputes over compensation; limited the time period during which data used in support of a follow-on application require compensation; and repealed the statutory prohibition that had barred the agency from disclosing or relying on data that the submitter had labelled as "trade secret" information. *Id.* §§ 2, 15 (codified at 7 U.S.C. §§ 136a(c)(1)(D), 136h (1982)). In addition, to reward innovation, Congress granted the submitter a ten-year period of exclusive use for data involving new active ingredients or new uses of previously registered products. *Id.* § 2, 7 U.S.C. § 136a (c)(1)(D); *see Chevron Chemical Co. v. Costle*, 641 F.2d at 113-14.

In short, the 1978 amendments reflected the coalescing of four important public objectives, each of which plainly falls within Congress' legislative power. First, the Act provides a regulatory mechanism intended to assure that only safe and effective pesticides are sold in interstate commerce. Second, by authorizing EPA to rely on data in its own files, Congress hoped to streamline the regulatory process, and thereby eliminate waste and duplication of effort. Third, by establishing a mechanism to compensate registrants whose data are used in approving follow-on registrations, Congress chose to spread the cost of assembling the data among all registrants that benefitted

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[6] *See* S. REP. No. 334, 95th Cong., 1st Sess. 3, 8, 30-31 (1977) (indicating Congress' dissatisfaction with the effect of the data requirements as an extension of patents beyond the seventeen-year statutory period of protection). *See also* 124 CONG. REC. S15303-04 (daily ed. Sept. 18, 1978) (remarks of Sen. Leahy); H.R. REP. No. 663, 95th Cong., 1st Sess. 18 (1977), *reprinted in* 1978 U.S. CODE CONG. & AD. NEWS 1988, 1991.

from the data. It thereby sought to minimize possible disincentives to innovation if initial registrants had to bear the entire cost of a registration application while potential competitors enjoyed a "free ride" on the initial registrant's costly studies. Finally, to minimize barriers to market entry resulting from the data submission requirements and thus promote competition, Congress reaffirmed the agency's right to use data in its files to approve follow-on applications for products the agency had already found to be safe and effective.[7]

B. Experience Confirms That the Goals of the Act Have Been Achieved, But They Will Be Undone If the Act Is Held to Effect an Unconstitutional Taking.

The record since Congress last amended the statute in 1978 shows that it has accomplished what Congress set out to do. As Congress predicted, section 3(c)(1)(D)

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[7] A scheme similar to FIFRA's data reliance scheme was adopted by Congress in 1976 to govern regulation of chemical substances and mixtures. *See* Toxic Substances Control Act ("TSCA"), Pub. L. No. 94-469, 90 Stat. 2006, 15 U.S.C. §§ 2603-29 (1982). That Act requires testing of certain potentially hazardous substances (TSCA § 4(a), 15 U.S.C. § 2603(a)), but exempts any firm whose product is equivalent to a substance for which data have been submitted and where testing would be duplicative (TSCA § 4(c)(2)(B), 15 U.S.C. § 2603(c)(2)(B)), if it pays "fair and equitable reimbursement" to the companies that sponsored the tests (TSCA § 4(c)(3)(A), 15 U.S.C. § 2603(c)(3)(A)). As in the case of FIFRA, Congress was concerned here with wasteful duplication and wished to avoid the anticompetitive effect of a scheme that required every firm to submit data, whether or not the substance of the data already was known to the Agency. *See* S. REP. No. 698, 94th Cong., 2d Sess. 12, 16, *reprinted in* 1976 U.S. CODE CONG. & AD. NEWS 4491, 4502, 4506.

In contrast to FIFRA and TSCA, section 505(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b) (1976), has been interpreted by FDA to require duplicative testing in connection with a new drug application. *See* 21 C.F.R. § 314.1 (1983). The Court considered a different aspect of this scheme last Term in *United States v. Generix Drug Corp.*, 460 U.S. ——, 103 S. Ct. 1298 (1983).

has removed unnecessary barriers to market entry created by the Act's data submission requirement and has facilitated the emergence of a competitive market environment. EPA still must examine each proposed pesticide product to confirm its safety and efficacy, but it no longer must ignore pertinent information in its own files. Similarly, registration applicants for follow-on products no longer must conduct years of costly studies to prove again and again what the Agency already can determine from data in its files.

Most competition in this industry comes from follow-on products. For example, of approximately sixty companies that have a registration for a four pound per gallon methyl parathion product (including Monsanto), at least 90% (including all three individual *amici*) hold follow-on registrations. Similarly, of the dozen or so companies that market a three pound per gallon dinitro product, at least two-thirds (including Drexel) hold follow-on registrations.

The approval of a follow-on application can produce almost immediate economic benefits to farmers and the public in the form of reduced prices, often even before the follow-on product reaches the market. For instance, through 1983, the Diamond Shamrock Corporation, a multinational conglomerate with annual sales of over $3 billion, has been the only registrant of technical chlorothalonil, a fungicide used on most of the American peanut crop, on soybeans and on various vegetables. Diamond Shamrock holds patents on chlorothalonil and hence has had no competition in the sale of that product.[8] Because these patents are about to expire, Griffin Corporation obtained a registration for technical chlorothalonil in January 1983. Until that time, Diamond Shamrock's product sold for approximately $23 per gallon wholesale. However, shortly after Griffin received its registration,

[8] EPA, Office of Pesticide Programs, *Agricultural Impact Analysis of Chlorothalonil* at 5 (Sept. 28, 1983).

Diamond Shamrock dropped its price to $18 per gallon, without even waiting for Griffin to begin marketing the product. This price reduction alone will save American farmers millions of dollars per year.[9]

The price for atrazine, which is used on approximately sixty-four million acres of crops in this country, also has dropped since follow-on registrations have been issued. In 1976, before the patent held by Ciba-Geigy Corporation expired, the wholesale price was approximately $13 per gallon. Since then, at least eight follow-on registrations have been issued (including to Griffin and Drexel), and the current price is approximately $7 per gallon. With approximately twenty million pounds of atrazine used each year, this price reduction has yielded enormous cost savings for this country's farmers.

A similar price reduction is likely in the domestic trifluralin market by 1985 when that patent, held by an Eli Lilly Company subsidiary, expires. This pesticide is used in the United States primarily on cotton and soybeans and also is sold abroad. In the United States, trifluralin is sold to distributors for approximately $28 to $30 per gallon (assuming a formulation of four pounds per gallon), while the price abroad, where multiple sellers compete with each other, is less than half the domestic price. Drexel Chemical Company already has received a trifluralin follow-on registration from EPA and expects to begin marketing the product in 1985 as soon as Eli Lilly's patent expires. The domestic price can be expected to drop substantially at that time, and the impact of this decrease will be widespread. PPA members' market evaluations show that in 1982 alone, approximately fifty-

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[9] *Id.* at 9. As EPA recognizes, price decreases are likely when a pesticide company suddenly faces competition, after having been "isolated . . . by patent or other similar protection." *Id.*

three million pounds of trifluralin were produced in the United States.[10]

If the Court affirms the decision below and invalidates the follow-on scheme, there appears to be no question that many initial registrants will seek to cancel existing follow-on registrations. For example, both Drexel Chemical Company and Griffin Corporation recently have received letters from the du Pont Company, the initial registrant of linuron, a pesticide for which both *amici* hold follow-on registrations, stating that du Pont intends to seek to nullify those registrations.[11] More generally, plaintiffs (including Monsanto) in a case pending in the Southern District of New York in which the FIFRA arbitration scheme has been found unconstitutional have urged that court to cancel all post-1978 follow-on registrations as well as to enjoin all future registrations under section 3(c)(1)(D). *See* Plaintiffs' Proposed Judgment and Order, ¶¶ 2, 3 (filed Oct. 5, 1983), *Union Carbide Agricultural Products Co. v. Ruckelshaus*, 19 Env't Rep. Cas. (BNA) 1650 (S.D.N.Y. 1983).

In the face of such cancellations, only one option would remain for current follow-on registrants which wish to compete vigorously with the initial registrant: to duplicate and submit to EPA data already in the files. This would not, however, be economically feasible. Most of Drexel Chemical Company's principal pesticide products, for example, have follow-on registrations issued since

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[10] *See also* EPA, OFFICE OF RESEARCH & DEVELOPMENT, GUIDELINE FOR THE DISPOSAL OF SMALL QUANTITIES OF UNUSED PESTICIDES at 161, table C (1975) (the atrazine production volume in the United States in 1971 was 25 million pounds).

[11] *See* Letters from Louis Del Vecchio, Legal Department, du Pont de Nemours & Company, to Michael T. Smith, Vice-President, Drexel Chemical Company, and John D. Elliot, Vice-President, Griffin Corporation, Nov. 8, 1983.

1978. If the company now were required to spend approximately $1.8 to $2.9 million per active ingredient to generate its own data,[12] it would have to spend as much as $5.8 million, almost one-fourth the company's annual sales volume, to continue marketing its primary products.

Similarly, Drexel now has over twenty-five applications for follow-on registrations with different active ingredients pending at EPA, which cannot be processed because of the district court's injunction. The cost of testing for these products could reach $72 million, almost three times Drexel's annual sales volume. Moreover, Drexel's circumstances are hardly unique. EPA estimated in its application to Justice Blackmun to stay the judgment below that over the course of a year, applications for 1,700 to 2,200 new products will be precluded or delayed because of the district court's decision.[13]

Furthermore, these are not tests that can be duplicated overnight; many are extremely time consuming, including some that will take as long as four years to complete.[14] This delay in obtaining registrations will handicap the smaller companies seeking to return to the market because of the substantial headstart gained by the few large firms that already have received registrations based on their own data. EPA estimates that less than 25% of the anticipated registration applications for new agricultural pesticides or amendments thereto are likely to qualify for registration if the data reliance scheme were invalidated.[15]

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[12] *See* note 1 *supra*.

[13] Affidavit of Edwin L. Johnson, Director, EPA Office of Pesticide Programs, submitted in support of EPA's Application for a Stay of Judgment of the United States District Court for the Eastern District of Missouri Pending Direct Appeal, July 1983, ¶ 6.

[14] *Id.* ¶ 5.

[15] *Id.* ¶6.

Finally, sharp price increases are almost certain to follow a decision that results in the cancellation of existing follow-on registrations. This will occur in two ways. First, registrants who have submitted data, no longer facing competition from follow-on sellers, will be able to raise their prices with impunity.[16] Second, even if some of the small pesticide firms can afford to sponsor their own tests and eventually return to the market, the cost of market entry will be substantially higher than at present, forcing them to set their own prices at significantly higher levels than they do today.

In sum, the sharp decline in competition that inevitably would follow invalidation of the 1978 amendments would affect not only the viability of most small pesticide companies, but also, in turn, would increase the costs of American farmers and the prices they charge for their products. As we show in Section II of this brief, nothing in the Fifth Amendment compels such a calamitous result. To the contrary, Congress enacted section 3(c)(1)(D) of FIFRA under its broad Commerce Clause authority to prevent such consequences, and plainly the legislation has accomplished what Congress intended.

II. EPA'S USE OF DATA SUBMITTED BY ONE REGISTRANT TO ESTABLISH THE SAFETY AND EFFICACY OF A SECOND APPLICANT'S PRODUCT DOES NOT CONSTITUTE A "TAKING."

In holding that FIFRA unconstitutionally effected a taking of Monsanto's property, the district court rejected at least a half century of modern jurisprudence confirming the full breadth and scope of Congress' authority to

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[16] For example, in today's market, over 40 million pounds of 2, 4-dichlorophenoxyacetic acid are applied annually on grain crops such as corn, wheat, barley, rye and oats, and some two dozen firms, including Falls Chemicals, hold follow-on registrations. If these firms are forced out of the market because their follow-on registrations have been cancelled, the data submitters for those products will be free to raise their prices substantially.

enact "public program[s] adjusting the benefits and burdens of economic life to promote the common good" [17] and sharply limiting the judicial reexamination of the purpose for which Congress has exercised its legislative power.[18] More specifically, the district court applied the Takings Clause in a wooden and impractical manner that totally disregards the balancing approach called for by this Court's decision in *Penn Central Transportation Co. v. New York City*, 438 U.S. 104, 130-31 (1978) (the Court must examine "the character of the action . . . [and] the nature and extent of the interference with rights in the [property] as a whole"). *See also Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 432 (1982). Its conclusion that this scheme effects an unconstitutional taking rests largely on its failure to appreciate the fact that, as described above, this scheme serves important public interests that Congress was entitled to promote. *See, e.g., Berman v. Parker*, 348 U.S. 26, 32-33 (1954).

A. As a threshold matter, and as the Third Circuit has held (*see Chevron Chemical Co. v. Costle*, 641 F.2d 104, 114-16, *cert. denied*, 452 U.S. 961 (1981)), the district court overstated the nature of Monsanto's property interest. One can assume that so long as the data remained entirely in Monsanto's possession they were

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[17] *Penn Central Transp. Co. v. New York City*, 438 U.S. 104, 124 (1978); *see Usery v. Turner Elkhorn Mining Co.*, 428 U.S. 1, 15 (1976).

[18] *See, e.g., Hodel v. Indiana*, 452 U.S. 314, 323-24 (1981) ("court may invalidate legislation enacted under the Commerce Clause only if it is clear that there is no rational basis for a congressional finding . . . that there is no reasonable connection between the regulatory means selected and the asserted ends"); *Ferguson v. Skrupa*, 372 U.S. 726, 729 (1963) ("[u]nder the system of government created by our Constitution, it is up to legislatures, not courts, to decide on the wisdom and utility of legislation"); *Berman v. Parker*, 348 U.S. 26, 32 (1954) ("role of the judiciary in determining whether [the taking] power is being exercised for a public purpose is an extremely narrow one").

treated as trade secrets entitled to some form of legal protection. But Monsanto generated the data to receive a regulatory benefit, and consistent with that purpose, chose to apply for a registration which necessarily involved disclosure of the data to EPA. In such a circumstance, Monsanto has no constitutional right to set the terms under which it turns information over to a government agency.[19] By voluntarily availing itself of the benefits of the pesticide registration program, Monsanto acquiesced in "the burdens as well as the benefits" of the program. *Almeida-Sanchez v. United States*, 413 U.S. 266, 271 (1973); *see Chevron Chemical Co. v. Costle*, 641 F.2d at 115-16.

The district court's decision also has disturbing implications concerning federal/state relationships. Federal agencies receive data from private sources virtually every day. These agencies' operations easily could be hamstrung if their use of such data were restricted by state intellectual property laws. Regardless of whether the district court has correctly construed Missouri's trade secret law, reliance on state law to restrict the federal government's use of data in its own files is incompatible with the principle of the Supremacy Clause that "shield[s] federal installations and activities from regulation by the States." *Hancock v. Train*, 426 U.S. 167, 179 (1976). *See also Chevron Chemical Corp. v. Costle*, 641 F.2d at 116.[20]

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[19] While Congress obviously may accord protection to a private entity's voluntary data submission (*see, e.g.*, Trade Secrets Act, 18 U.S.C. § 1905 (1982); Federal Food, Drug, and Cosmetic Act § 301(j), 21 U.S.C. § 331(j) (Supp. V 1981)), the Constitution does not require it to do so.

[20] In relying on state trade secret law, the district court appeared to confuse internal use of agency data containing a private entity's trade secrets with public disclosure. As the Third Circuit pointed out in *Chevron*, neither state trade secret laws nor the federal Trade Secrets Act has anything to do with internal use. 641 F.2d at 115-16.

B. Even positing that data in EPA's files are the data submitter's "property" protected by the Fifth Amendment, the district court was flatly in error when it held that section 3(c)(1)(D) "unabashedly operates to further a private purpose." J.S. App. at 32a. In reaching this conclusion, the district court ignored the contrary conclusion of every other court that has addressed this issue, *viz.*, that FIFRA's data reliance provision promotes substantial public purposes. *See Chevron Chemical Co. v. Costle*, 641 F.2d 104, 116 (3d Cir. 1981), *aff'g* 499 F. Supp. 732, 740-42 (D. Del. 1980), *cert. denied*, 452 U.S. 961 (1981); *Petrolite Corp. v. EPA*, 519 F. Supp. 966, 974 (D.D.C. 1981). *See also Union Carbide Agricultural Products Co. v. Costle*, 632 F.2d 1014, 1018 (2d Cir. 1980), *cert. denied*, 450 U.S. 996 (1981) (denying a preliminary injunction to enjoin use of section 3(c)(1)(D)).

The correct view, demonstrated by these several decisions rejected by the court below, is supported by a number of facts. Most fundamentally, Congress' legislative authority under the Commerce Clause amply supports a regulatory scheme that conditions the right of a pesticide producer to market a product on submission of data to the government that establish that the product is safe and effective. There is no jeopardy to public health and safety in allowing EPA to rely on data already in its possession rather than requiring each applicant to generate its own test data, and this results in enormous savings of administrative costs and time spent in the registration process.

Furthermore, such a streamlined regulatory formula works to the benefit of all taxpayers as well as the applicants for registrations. A scheme that prohibited EPA from relying on data in its own files, thereby forcing each applicant to duplicate the health and safety data previously submitted, would waste scientific resources by diverting research and development expertise to unpro-

ductive uses.[21] The purpose of the statute is not to create a regulatory obstacle course that all pesticide marketers must complete to be eligible to market their products, but to erect a regulatory scheme that permits EPA to assure the public that all pesticides on the market are safe and effective. Because the purpose of the testing is to secure the information EPA needs to determine whether a pesticide is safe and effective, Congress plainly was entitled to fashion a regulatory scheme that provided EPA with that information without imposing on every applicant a make-work assignment to duplicate and submit to the agency information it already possesses.

In addition, by minimizing the barriers to entry caused by the regulatory scheme, the data reliance scheme fosters competition. That competition is one of the most important of the nation's public policies[22] and that Congress has ample power to promote competition[23] need no longer be argued. Moreover, because the products involved in follow-on registrations are either common chemical compounds or products with expired or soon to expire patents and therefore can be sold lawfully by anyone (subject, of course, to prior registration under FIFRA), Congress was entitled to structure the pre-marketing data submission requirement to minimize any barriers to new market entry created by the regulatory scheme itself. Congress

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[21] *See* S. REP. No. 970, 92d Cong., 2d Sess. 12-16, *reprinted in* 1972 U.S. CODE CONG. & AD. NEWS 4092, 4096-100; McGarity & Shapiro, *The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies*, 93 HARV. L. REV. 837, 845, 847 (1980).

[22] *See, e.g., United States v. Topco Assocs., Inc.*, 405 U.S. 596, 610 (1972) ("[a]ntitrust laws . . . are the Magna Carta of free enterprise"); *Northern Pac. Ry. v. United States*, 356 U.S. 1, 4 (1958) ("Sherman Act was designed to be a comprehensive charter of economic liberty aimed at preserving free and unfettered competition as the rule of trade").

[23] *See, e.g., United States v. Topco Assocs., Inc.*, 405 U.S. at 611-12.

has no constitutional obligation to transform the data submission requirement in FIFRA into a vehicle extending to initial registrants the equivalent of an indefinite patent monopoly for unpatented products.[24]

The district court's finding that "the trial record amply demonstrates [that] competition [in] the pesticide industry [is] healthy and vibrant" (J.S. App. at 32a) misses the point. Competition in this industry is largely the product of the 1978 legislation. Congress was concerned with the non-competitive environment that prior law had created, and adopted a reasonable statutory provision designed to change the conditions that concerned it.[25]

In any case, it was not the district court's province to second-guess Congress' judgment about the state of competition in the pesticide industry or to determine whether Congress had mandated too much competition. That is precisely the type of legislative judgment reserved to Congress. *See Hodel v. Indiana*, 452 U.S. 314, 326 (1981). The role of the judiciary in such circumstances is "an extremely narrow one"; Congressional findings of public purpose are "well-nigh conclusive." *Berman v. Parker*, 348 U.S. 26, 32 (1954). Once the existence of a valid public purpose has been determined, the fact that some private benefit incidentally flows from the regulatory scheme becomes irrelevant. *See id.*; *Thompson v. Consolidated Gas Utilities Corp.*, 300 U.S. 55, 77 (1937).

C. Given the district court's overstatement of Monsanto's property interest in the data and its failure to recognize the public purposes that underlie the regulatory action to which Monsanto objects, the conclusion that FIFRA effects an unconstitutional "taking" of Monsanto's property rests on an improper application of the principles described in *Penn Central Transportation Co. v. New York City*, 438 U.S. at 123-35. Moreover, in

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[24] *See* note 4 *supra* and accompanying text.

[25] *See* pp. 9-11 *supra*.

that case, this Court pointed out that "[a] 'taking' may more readily be found when the interference with property can be characterized as a physical invasion by government . . . than when interference arises from some public program adjusting the benefits and burdens of economic life to promote the common good." *Id.* at 124. Here, to the extent there is any interference with property, we are concerned with interference resulting from a public program rather than a physical invasion of property.

The district court concluded that use of Monsanto's data in EPA's files to approve a competitor's registration deprived Monsanto of the ability to exclude its competitors from the market. J.S. App. at 31a. While it is true that the right to exclude others is one of the attributes of a property interest, that factor alone does not establish a "taking." *See Pruneyard Shopping Center v. Robins*, 447 U.S. 74, 82-83 (1980). Monsanto has "failed to demonstrate that the 'right to exclude others' is so essential to the use or economic value of [its] property" that EPA's use of the data to register follow-on products amounts to a "taking." *Id.* at 84. At most, it deprives Monsanto of one strand of a bundle of property rights. *See Andrus v. Allard*, 444 U.S. 51, 65-66 (1979). Monsanto still retains the use of the data for its own purposes, although, of course, its principal value has been to provide EPA with a basis for registering Monsanto's product. Monsanto's investment expectation in generating the data therefore was achieved when it received the registration from EPA and began marketing the registered product. *See Penn Central Transportation Co. v. New York City*, 438 U.S. at 136-38.

To be sure, if Monsanto retained exclusive use of its own data, that would delay and perhaps prevent competitors from entering the market. The effect would be to reduce the level of competition in the market and undoubtedly to increase Monsanto's profits. But "regulations [that] prevent the most profitable use of . . . prop-

erty" do not thereby effect a "taking." *Andrus v. Allard*, 444 U.S. at 66. "[L]oss of future profits—unaccompanied by any physical property restriction—provides a slender reed upon which to rest a taking claim." *Id.*

Finally, the mere fact that regulations "designed to promote the general welfare . . . burden some more than others" does not transform regulation into a "taking." *See Penn Central Transportation Co. v. New York City*, 438 U.S. at 113. Yet it also is significant that Monsanto and other initial registrants have not been singled out to bear all the burdens of the regulatory scheme while others enjoy its benefits. Monsanto benefits from the scheme by receiving a regulatory license to market its product with a *de facto* government testimonial that the product is safe and effective. Moreover, as noted above, the scheme seeks to mitigate the burdens on prior registrants whose data may be used in granting registrations to other applicants by spreading the cost of testing and assembling the data among all who benefit from the data. The fact that Congress formulated a scheme that avoids a disproportionate burden on any one segment of the industry indicates that any reduction in the value of Monsanto's property stems from regulation to promote the general welfare rather than from a "taking." *See Pruneyard Shopping Center v. Robins*, 447 U.S. at 82-83; *Penn Central Transportation Co. v. New York City*, 438 U.S. at 124-25.

III. BECAUSE THE CONSTITUTIONALITY OF THE STATUTORY ARBITRATION SCHEME IS NOT RIPE FOR ADJUDICATION IN THIS LAWSUIT, THE DISTRICT COURT SHOULD BE DIRECTED TO DISMISS THE COMPLAINT.

In addition to addressing FIFRA's follow-on registration scheme, the district court also concluded that the arbitration provision in section 3(c)(1)(D)(ii) is unconstitutional. It held that the arbitration scheme fails to meet constitutional requirements for affording just

compensation to remedy a Fifth Amendment "taking."[26] Absent a "taking," however, there is no requirement for just compensation. Therefore, if the district court's "taking" conclusion is rejected, the constitutionality of the arbitration remedy is not ripe for adjudication, and the proper disposition of this case is to reverse the district court's judgment in its entirety and to direct it to dismiss the complaint.

Even if this Court were to affirm the district court's taking conclusion, however, it still would be premature for any court hearing this lawsuit to determine whether the arbitration mechanism satisfies constitutional requirements for affording just compensation. Monsanto has not invoked the arbitration mechanism to resolve a compensation dispute with a follow-on registrant, and there is no assurance that Monsanto ever will have occasion to resort to arbitration.[27] The Act permits the original data submitter and the follow-on applicant to fix the terms and amount of compensation by agreement or to set their own procedures to arrive at such an agreement, and provides for binding arbitration only if the parties after ninety days have been unable to agree on the amount of compensation. FIFRA § 3(c)(1)(D)(ii), 7 U.S.C. § 136a(c)(1)(D)(ii). It is conjectural at this point whether Monsanto will be unable to agree on the terms of compensation with follow-on registrants and whether it therefore will be forced to pursue the arbitration remedy. Monsanto will have ample opportunity to test the constitutional validity of the arbitration scheme should it ever

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[26] As even Monsanto has noted, nothing in the opinion below addresses the validity of the arbitration scheme apart from its adequacy as a means of providing just compensation. *See* Motion to Affirm at 24 & n.24.

[27] By contrast, the meaning of compensation and the authority of arbitrators under FIFRA is squarely raised in *PPG Industries, Inc. v. Stauffer Chemical Co.*, No. 83-1941 (filed July 7, 1983), now pending in the United States District Court for the District of Columbia.

invoke that mechanism. *See Babbitt v. United Farm Workers National Union*, 442 U.S. 289, 304-05 (1979). Accordingly, if the Court affirms the portion of the district court's judgment relating to the taking claim, it should still reverse its decision on the arbitration scheme and direct it to dismiss that portion of the complaint.[28]

CONCLUSION

The district court's judgment should be reversed and the case remanded to that court with directions to dismiss the complaint.

Respectfully submitted,

DAVID B. WEINBERG
WILLIAM R. WEISSMAN
SUSAN D. SAWTELLE
WALD, HARKRADER & ROSS
1300 Nineteenth Street, N.W.
Washington, D.C. 20036
(202) 828-1200
Attorneys for the Pesticide Producers Association, Drexel Chemical Company, Falls Chemicals, Inc., and Griffin Corporation

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[28] Another very practical reason to direct the district court to dismiss the complaint is to avoid any further effort by Monsanto to obtain indirectly the same anticompetitive relief it has obtained to date in this case, by arguing that some constitutional taint of the arbitration scheme requires that the entire FIFRA follow-on procedure be invalidated. This is precisely the position that Monsanto has asserted in the pending *Union Carbide* case (*see* p. 14 *supra*) and presumably would assert on remand if the opportunity were presented.